

REMARKS

Applicants' representatives take this opportunity to thank Examiner Parkin for the very helpful teleconferences on October 7, 2003, October 20, 2003, and November 19, 2003. In the teleconference on November 19, 2003, Applicants' representative, Jennifer Chheda, and Examiner Parkin discussed a proposed draft set of claims. Examiner Parkin informed Applicants' representative that the proposed claim amendments in the draft set of claims were allowable. Accordingly, Applicants present herein those claim amendments for entry into the application.

In order to expedite the prosecution of the present application and without conceding to the validity of the Examiner's rejections, Applicants have amended claims 2, 3, 11, 12, 14, 15, 17 and 57-69. In particular, Applicants have amended independent claim 2 to recite an assay for identifying a substance that inhibits the interaction of an influenza virus nucleoprotein with the host cell protein nucleoprotein interaction-1 (NPI-1), NPI-2, NPI-2, NPI-3, NPI-4, NPI-5, or NPI-6. Applicants have amended independent claim 57 to recite an assay for identifying a substance that inhibits the interaction of an influenza virus nucleoprotein with NPI-1 comprising contacting the influenza virus nucleoprotein with the peptide fragment of NPI-1 consisting of amino acid residues 262-527 of NPI-1 in the presence of a substance. Applicants have amended independent claim 58 to recite an assay for identifying a substance that inhibits the interaction of an influenza virus nucleoprotein with NPI-1 comprising contacting the influenza virus nucleoprotein with a fusion protein comprising NPI-1 or amino acid residues 262-527 of NPI-1 in the presence of a substance.

Dependent claims 11, 12, 14, 17, and 59-69 have been amended to correct antecedent basis for the claims in view of the amendments to claim 2, 57 and 58. Dependent claim 3 has been amended to correct a typographical error in the spelling of the term nucleoprotein. The claim amendments are fully supported by the specification of the present application, see, *e.g.*, page 18, line 19 to page 30, line 9 and Example 6 at page 34 of the specification, and do not represent new subject matter. Claims 2-8, 11, 12, 14-17 and 57-74, therefore, will be pending upon entry of the present amendment.

Applicants believe that the present amendments to the claims address the Examiner's concerns and place the application into condition for allowance. As such, Applicants respectfully request that the remarks and amendment made herein be entered and fully considered.

**The Rejection Under 35 U.S.C. § 112,
First Paragraph, Should Be Withdrawn**

Claims 2-8, 11, 12, 14-17, and 57-74 are rejected under 35 U.S.C. §112, first paragraph, as not enabled by the specification. The Examiner contends that the claims are excessive in breadth and that the specification fails to provide sufficient guidance to enable one skilled in the art to practice the claimed invention. In particular, the Examiner contends that the specification fails to provide: (1) sufficient guidance regarding host cell proteins that are capable of binding specifically to influenza virus nucleoprotein (NP); (2) sufficient guidance regarding the molecular determinants modulating the specific binding interactions between host cell proteins and influenza virus NP; (3) sufficient guidance regarding host cell proteins and fragments thereof, as well as fragments of influenza virus NP, that will function in the recited screening assays; and (4) a sufficient number of working embodiments. For the reasons detailed below, Applicants respectfully assert that the rejection under 35 U.S.C. § 112, first paragraph, for lack of enablement cannot stand and should be withdrawn.

In order to expedite prosecution of the application and without conceding to the validity of the Examiner's rejection, Applicants have amended independent claim 2, as suggested by the Examiner in the Advisory Action, mailed May 20, 2003, to recite particular host cell proteins, namely NPI-1, NPI-2, NPI-3, NPI-4, NPI-5 and NPI-6. Applicants have also amended independent claim 57 to recite the NPI-1 peptide fragment consisting of amino acid residues 262-527 of NPI-1 disclosed in Example 6 of the specification of the present application. Further, Applicants have amended independent claim 58 to recite a fusion protein comprising NPI-1 or the peptide fragment consisting of amino acid residues 262-527 of NPI-1 disclosed in Example 6 of the specification of the present application.

The specification provides sufficient guidance to enable one of skill in the art to identify substances that inhibit the interaction between the particular host cell proteins recited in the pending claims and the influenza virus nucleoprotein (NP). The specification describes six host cell proteins, nucleoprotein interactor ("NPI")-1, NPI-2, NPI-3, NPI-4, NPI-5, and NPI-6, that interact with the influenza virus NP. For clarity of discussion, the specification provides particular detail regarding the isolation and characterization of NPI-1, and its interaction with the influenza virus NP protein (*see* the specification of the present application at page 8, *ll.* 9-26; Example 6 at page 34, line 1 to page 44, line 2). In the case of NPI-1, the complete nucleotide sequence of the cDNA and the protein encoded by it are

provided and biochemical characterization assays are presented that have assessed the interaction with influenza virus NP (*see* the specification of the present at page 11, line 1 to page 13, line 35). Further, as the Examiner has pointed out, the specification describes a peptide fragment of the host cell protein NPI-1 consisting of amino acids 262-526 that binds to the influenza virus nucleoprotein. Thus, Applicants respectfully assert that the specification does provide sufficient guidance to enable one of skill in the art to identify substances that inhibit the interaction between the particular host cell proteins of the claimed invention and influenza virus nucleoprotein.

In view of the foregoing, Applicants submit that the invention as claimed is fully enabled by the specification of the instant application. Accordingly, Applicants respectfully assert that the rejection under 35 U.S.C. §112, first paragraph, cannot stand and should be withdrawn.

CONCLUSION

Applicants believe that the present claims meet all of the requirements for patentability. Entry and consideration of the foregoing amendment and remarks into the file of the above-identified application is respectfully requested. Withdrawal of all the rejections and reconsideration of the claims is requested.

If any issues remain, the Examiner is requested to telephone the undersigned at (212) 790-6431.

Respectfully submitted,

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